



Tvardi Therapeutics' TTI-101 Receives Orphan Drug Designation for Idiopathic Pulmonary Fibrosis

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Houston, TX – May 26, 2022 – Tvardi Therapeutics, Inc. ("Tvardi"), a privately held, clinical-stage biopharmaceutical company focused on the development of STAT3 inhibitors, today announced that its lead product, TTI-101, has been granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) for the treatment of idiopathic pulmonary fibrosis (IPF).

The FDA has the authority to grant ODD to any drug or biological product which shows promise in treating rare diseases or conditions that affect fewer than 200,000 people in the U.S. IPF is one such rare disease Tvardi is targeting with the use of TTI-101. IPF is typically fatal within two to three years of diagnosis.

TTI-101 is an orally-delivered, small molecule, direct STAT3 inhibitor. STAT3 has emerged as a central node of fibrosis and has been found to accumulate in the fibrotic lungs of IPF patients. STAT3 plays a major role in many of the cellular processes that drive the development and progression of fibrosis including clotting and coagulation, inflammatory cell migration, fibroblast proliferation, and extra-cellular matrix deposition.

"We are pleased to receive Orphan Drug Designation from the FDA for TTI-101 for the treatment of IPF," said Imran Alibhai, PhD, CEO of Tvardi. "This designation provides further support for the development of TTI-101, which has shown promise in treating diseases in which STAT3 plays a critical role. Tvardi is dedicated to pursuing treatment of STAT3-driven diseases with TTI-101, beginning with a Phase 1 trial in oncology and now advancing to Phase 2 clinical trials in both IPF and oncology."

The ODD will allow Tvardi to receive partial tax credits for qualified IPF clinical trials and benefit from exemptions from user fees for new drug applications. In addition, the ODD will qualify the TTI-101 program for seven years of market exclusivity following FDA approval of TTI-101 as a treatment of IPF.

About Tvardi Therapeutics

Tvardi is a privately held, clinical-stage biopharmaceutical company developing small molecule inhibitors of STAT3, a key regulatory protein positioned at the intersection of many signaling pathways integral to the survival and immune evasion of cancer cells. STAT3 also plays a central role in the pathogenesis of many inflammatory and fibrotic diseases including IPF. To learn more, please visit [Tvardi Therapeutics](#).

About TTI-101

Tvardi's lead product, TTI-101, is currently under investigation in a Phase 1 single agent multicenter clinical trial in patients with advanced solid tumors. This study has demonstrated that TTI-101 is well tolerated and has clinical activity across a broad range of tumors. Pre-clinical studies have also demonstrated that STAT3 inhibition with TTI-101 reverses fibrosis and restores lung function in models of IPF. Commencing in 2022, TTI-101 will be investigated in Phase 2 IPF and oncology clinical trials. For more information on the ongoing clinical trials of TTI-101, please visit [Tvardi Therapeutics Clinical Trials](#).

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